Comments on the NTP's Report on Carcinogens (RoC) Process

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Recommendations

Strengthen the scientific quality

 Enhance public participation processes in the development of RoC actions

 Clarify listing/delisting criteria used for the RoC

Scientific Quality

- The foundation of RoC listings and delistings
 - comprehensive and thorough review and interpretation of the best available science
 - scientific experts need to be involved
 - conducted in a manner that fosters scientific dialog
 - transparent decision making, open meetings and stakeholder involvement
- Any changes to the RoC contemplated by NTP should be focused on ensuring these fundamental principles are enhanced
- NTP's efforts to revise the RoC process will be advanced by activities to address Data Quality and Peer Review directives of OMB

Public & Stakeholder Participation

- Open & transparent process
- Adequate time to engage
- Opportunity for meaningful input at appropriate points
- Recognition that comments & interchange is considered fully

ACC's Recommendations

 NTP consider adapting and building on the interactive scientific model put into practice in the CERHR process

- Adaptation of the CERHR process:
 - Comprehensive & thorough background document
 - Participation in drafting/writing document by subjectmatter experts
 - Opportunity for meaningful scientific input early on in the process: latest studies, mode of action data, etc.

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NTP Center for the Evaluation of Risks to Human Reproduction



NTP Center Report

CC Recommends Expert Panel

Background Information
Expert Panel Conclusions
New data
NTP position
Public comments

Approval, NTP, Assoc. Director

Nominations reviewed by CC

Chemicals recommended

Open nomination process



Meeting Announcement; Public comment

CC Review

NTP Center Report Transmitted

Expert Panel meeting; public

comment

CC Recommends chemicals for

review

Public comment

Draft report

Approval, NTP, Assoc. Director

- Federal agenciesState agenciesPublicScientific community

Approval, NTP, Assoc. Director

Public comment

Public comment

Expert Panel Report

Recommended Process NTP Consider for Strengthening the RoC

Listing & Delisting Final Expert Panel Report Nominations **RoC Interagency Committee** Release of Expert Panel Deliberations report and requests public comment Notice of candidate chemicals & request for RoC staff prepare NTP public comment Draft Monograph **RoC Interagency Committee** Review Public Review of NTP Draft Monograph Chemicals announced & request for new data; planned studies; information on exposure and use patterns; nominations of NTP Interagency Executive individuals qualified to serve on Committee Approval the Expert Panel Development of Review Final Monograph Submitted to Draft of Expert Panel Report Director NTP and Secretary DHHS for Approval and Publication Request for Scientific & Public Review/Comments on the Review Draft Expert Panel Report Secretary DHHS approval & Monograph is made publicly available & distributed to **Expert Panel Meeting** federal and state agencies & interested stakeholders

Criteria for Listing/Delisting

- "Known to be a human carcinogen" determination should only be made if there is
 sufficient evidence of carcinogenicity from
 epidemiological or clinical studies that
 indicate a causal relationship between
 exposure to the agent and human cancer.
- A clear distinction between "known to be a human carcinogen" and "reasonably anticipated to be a human carcinogen" is sound public policy.
- Mechanistic or other scientific information should be used in reaching a determination of "reasonably anticipated to be (or not to be) a human carcinogen"